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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION,
and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

**PLAINTIFFS' OPPOSITION TO
DEFENDANT SENORX, INC.'S MOTION
FOR PARTIAL SUMMARY JUDGMENT
OF NON-INFRINGEMENT ('813 PATENT,
CLAIMS 11 & 12; '204 PATENT, CLAIMS 4
& 17; AND '142 PATENT, CLAIM 6)**

Date: June 25, 2008

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Judge: Hon. Ronald M. Whyte

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Plaintiffs Hologic, Inc., Cytac Corp., and Hologic L.P. (collectively, “Hologic”) hereby oppose SenoRx, Inc.’s (“SenoRx”) Motion for Summary Judgment of Non-Infringement of claims 11 and 12 of U.S. Patent No. 5,913,813 (the “‘813 patent”) and claims 4 and 17 of U.S. Patent No. 6,413,204 (the “‘204 Patent”).¹

PRELIMINARY STATEMENT

In its Motion for Summary Judgment of Non-Infringement (Dkt. No. 131), SenoRx asks this Court to declare as a matter of law that its accused Contura Multi-Lumen Balloon Applicator does not meet specific claim elements of the ‘813 and ‘204 patents.² On all counts, SenoRx is wrong. Far from showing non-infringement, even the scant evidence produced to date establishes that SenoRx’s Contura meets each element of the disputed claims. SenoRx does nothing more than argue that the Contura can be used in non-infringing ways, and that SenoRx and others have used it in ways that do not infringe. Under fundamental principles of patent law, that is irrelevant to infringement of apparatus claims.

Hologic’s patents-in-suit³ all relate to life-saving, radionuclide-based devices for treating proliferative tissue diseases, such as cancer, following the surgical removal of a tumor (known as a “resection”) – for example, in a woman’s breast. The specific treatment technique is called “interstitial brachytherapy,” an alternative to whole breast irradiation, in which a balloon catheter is inserted into a cavity created by the resection of diseased tissue to enable doctors to irradiate the remaining cancer cells along the cavity margins at close range. Emitting radio-therapeutic rays from close range allows precise targeting of the diseased tissue while minimizing the necrosis of healthy tissue. In the 1990s, engineers from a start-up company called Proxima Therapeutics, Inc. (Hologic’s predecessor)

¹ [REDACTED] Hologic has agreed to withdraw its assertion of claim 6 of the ‘142 patent. Therefore, it is not discussed herein.

² The claim elements at issue are “predetermined constant spacing” (as used in the ‘813 patent); “predetermined spacing” (as used in the ‘204 patent); “plurality of radioactive solid particles” (the ‘813 patent); and “plurality of solid radiation sources” (the ‘204 patent).

³ All three patents are related. The ‘813 patent is the parent. The ‘204 and ‘142 patents are both continuations-in-part of the ‘813 patent.

1 researched and developed improved devices and methods for performing brachytherapy. In the end,
2 Proxima revolutionized interstitial breast brachytherapy with its development of a novel balloon
3 catheter system, later commercialized as MammoSite, for delivering a radiation source directly to the
4 target breast tissue. The patents-in-suit are the fruits of those collective efforts, describing and
5 claiming many different device configurations, embodiments, and techniques for performing these
6 procedures. REDACTED

7 [REDACTED] See Dkt. No. 8 at 3-6 (Hologic's
8 Motion for Preliminary Injunction).

9 The claimed inventions are broad. Proxima's inventors conceived of and claimed, for example,
10 an apparatus that comprises an "inner spatial volume" located inside an outer, expandable surface (*e.g.*,
11 a balloon) in which the spacing between the inner and outer volumes remains generally constant during
12 treatment to produce a substantially uniform radiation dose profile or shape. *See, generally*, the
13 asserted '813 and '204 patent claims. The inventors also envisioned procedures in which, depending
14 on the shape of the surgical cavity and the target tissue, it would be advantageous to produce an
15 asymmetric radiation dose profile. Their efforts in the latter regard culminated in the '142 patent –
16 which claims an apparatus capable of producing asymmetrically-shaped dose profiles. The end result
17 of Proxima/Hologic's R&D is a family of patents covering a wide variety of devices for performing
18 interstitial brachytherapy. They describe, for example, emitting rays from a centrally-located position
19 within the balloon, using an asymmetrical position, using a single emission location, and emitting rays
20 from multiple locations, among others.

21 By any objective analysis, and largely by SenoRx's own admissions, the Contura is a
22 combination of many of the above-described inventions. Conceptually, the gist of SenoRx's argument
23 is that although Hologic owns patents covering devices that do A, B, C, and D, the Contura does not
24 infringe because, when it performs A, it does not simultaneously perform B, C, or D. SenoRx also
25 asserts that the Contura does not infringe because, when the Contura does B, it does something else
26 that is not patented. These arguments have no merit. The fact that the Contura does not infringe all of
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1 the asserted claims all of the time or at the same time does not mean that it does not infringe any of
2 them. To the contrary, as designed and intended for use, *it infringes all of the asserted claims*.

3 SenoRx's non-infringement arguments regarding the "predetermined spacing" elements are
4 flawed on multiple grounds. *First*, SenoRx applies a method claim analysis to apparatus claims – *i.e.*,
5 SenoRx ignores the Contura's structure and focuses on one specific way in which it can be used.
6 However, except in a means plus function context, infringement of an apparatus claim depends on
7 structural limitations, not upon statements of function. *Second*, SenoRx insists that Contura users
8 typically employ more than one "dwell point" during a procedure, and that some users employ the
9 outer, asymmetrically-positioned lumens. Hologic does not dispute that. The point, however, is that if
10 even one of the dwell positions is located in the center of the central treatment lumen (which is not
11 only possible, but is typically the case), the device exhibits a "constant spacing" between the "inner
12 spatial volume" and the Contura's balloon wall – and SenoRx infringes.⁴ SenoRx even concedes that
13 at each dwell location (including at the balloon center), the radionuclide *stops* to deliver radiation.
14 Thus, even under its own flawed claim construction, SenoRx infringes. In short, the Contura can be
15 (and is) used with a radionuclide at a central location within the balloon, thereby meeting the "constant
16 spacing" limitation. For purposes of infringement, whether the user *also* employs other lumens or
17 dwell points does not matter.

18 SenoRx's further non-infringement argument with respect to the terms "plurality of radioactive
19 solid particles" ('813 patent) and "plurality of solid radiation sources" ('204 patent) likewise has no
20 merit. SenoRx wrongly couches the dispute as a disagreement over the meaning of the word
21 "plurality." That is not the issue. The focus of the "plurality" claim terms is on emitting
22 radiotherapeutic rays from *multiple locations* so as to achieve a "desired composite profile" – as
23 distinguished from embodiments that emit radiation from a single location. Under the plain meaning
24 of these terms as used by the patentee, the Contura literally infringes because it can (and does) provide
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26 ⁴ While not at issue in this Motion, Hologic agrees that in some instances, SenoRx and others may
27 use *only* the Contura's outer, asymmetrically-placed lumens. But the device is still capable of being
28 used, and is typically used, with a radionuclide in the central lumen. It therefore infringes all the
asserted claims.

1 for the positioning of the radiation source in multiple locations to achieve a desired resultant profile.
2 In any event, even under SenoRx's claim construction, as set forth below, the Contura meets these
3 claim elements under the doctrine of equivalents.⁵

4 Viewing the evidence in a light most favorable to Hologic, and resolving all inferences in favor
5 of Hologic, SenoRx has not and cannot meet its burden of establishing as a matter of law that the
6 Contura device does not meet the disputed claim elements. The Motion must be denied.

7 ARGUMENT

8 I. LEGAL STANDARD FOR SUMMARY JUDGMENT

9 A court may grant a motion for summary judgment only if the moving party shows that there is
10 "no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter
11 of law." Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable jury
12 could find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). To
13 defeat SenoRx's Motion, Hologic is not required to present evidence resolving all material factual
14 issues in its favor; "rather, all that is required is that sufficient evidence supporting the claimed factual
15 dispute be shown." *Id.* at 249; *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d
16 1550, 1560-61 (Fed. Cir. 1995). At the summary judgment stage, the nonmoving party's version of
17 any disputed issue of fact is presumed correct. *Arizona v. Maricopa County Medical Soc.*, 457 U.S.
18 332, 339 (1982). Thus, the evidence of the nonmovant, Hologic, is to be accepted, and all justifiable
19 inferences are to be drawn in Hologic's favor. *Anderson*, 477 U.S. at 255.

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II. SENORX’S ACCUSED DEVICE MEETS THE “PREDETERMINED CONSTANT SPACING” LIMITATION OF THE ‘813 PATENT (CLAIMS 11 & 12)⁶

In the Xoft case⁷, the Court construed the term “predetermined constant spacing” in the ‘813 patent. Su Decl., Ex. B at 6-7 (Claim Construction Order in Xoft litigation). Hologic agrees with the Court’s construction. SenoRx argues that the Court is wrong and seeks to narrow the claim by adding extra limitations, emphasized below:

Term	Hologic’s Construction (the Court’s prior construction)	SenoRx’s Construction
“predetermined constant spacing . . . between said inner spatial volume and the radiation transparent wall”	Spacing predetermined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical or constant along a radial plane if the outer chamber is not spherical.	<i>Fixed</i> spacing, predetermined by one skilled in the art <i>before administering radiation</i> , between the wall or edge of the inner spatial volume and the wall of the expandable surface element, when inflated, <i>which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the expandable surface element is the same (i.e., the inner spatial volume and expandable surface element are concentric and the same shape).</i>

In its Motion, SenoRx asks the Court to declare as a matter of law that SenoRx does not infringe the “predetermined constant spacing” limitation of the ‘813 patent – suggesting that no reasonable jury could conclude otherwise. In fact, the opposite is true. Based on SenoRx’s own documents and admissions, under *either* party’s proposed claim construction, the Contura meets the “predetermined constant spacing” limitation in multiple ways. Because direct, contributory, and induced infringement is manifest, SenoRx’s Motion must be denied.

⁶ Claims 11 and 12 of the ‘813 patent both depend from claim 1, which contains the “predetermined constant spacing” language.

⁷ Two of the three patents-in-suit (the ‘813 and ‘204 patents) were asserted in a prior action in this Court entitled *Xoft, Inc. v. Cytoc Corp. et. al.*, Case No. C-05-05312 RMW [“Xoft litigation”]. Each of the terms disputed in this Motion was already litigated, briefed, and construed by the Court in that case. Su Decl., Ex. B (Claim Construction Order in Xoft litigation).

1 **A. The Contura Directly Infringes the Asserted Claims of the ‘813 Patent**

2 **1. The Contura Meets the “Predetermined Constant Spacing”**
 3 **Limitation Because It Can Emit Radiation from a Central Dwell**
 4 **Point**

5 SenoRx’s contention that the Contura does not meet the “predetermined constant spacing”
 6 limitation of the ‘813 patent is based on the false premise that the asserted claims are “method” rather
 7 than “apparatus” claims. SenoRx appears to admit that where multiple dwell points are used during
 8 radiotherapy, the radionuclide stops for a period of time at each location – and that where the central
 9 lumen is used, one of those locations may be in the center of the balloon. Nonetheless, SenoRx
 10 contends it does not infringe because the radionuclide *might also* emit radiation from other dwell
 11 points if other dwell points are used. In other words, a user can employ a method of use by which the
 12 spacing between the radionuclide and the balloon wall changes, *i.e.*, because the radionuclide is
 13 stepped through different dwell points rather than emitting radiation from a single point. But that
 14 argument is fundamentally flawed and ignores important distinctions between apparatus and method
 15 claims.

16 Infringement of an apparatus claim is determined based on the capabilities of an accused
 17 device’s structure, not its actual method(s) of use. *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*,
 18 909 F.2d 1464, 1468 (Fed. Cir. 1990) (“Apparatus claims cover what a device *is*, not what a device
 19 *does.*”); *In re Michlin*, 256 F.2d 317, 320 (C.C.P.A. 1958) (“It is well settled that patentability of
 20 apparatus claims must depend upon structural limitations and not upon statements of function.”); *NTP,*
 21 *Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005) (distinguishing between
 22 method claims and apparatus claims for the purpose of determining infringement under section
 23 271(a)).

24 Here, it is undisputed that the Contura contains five treatment lumens, one of which is centrally
 25 located along the balloon’s longitudinal axis. Dkt. No. 131 at 12-14 (Motion); *see* figure below. In
 26 one method of use, the radiation source may be stepped-through multiple dwell points, *stopping* for a
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9 predetermined period of time at each location to emit radiation. Dkt. No. 131 at 14-15 (Motion). REDACTED

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11 Users can decide which lumen(s) to use, which dwell position(s) to

12 employ within the lumen(s), and the duration of each dwell time. Su Decl., Ex. C at SRX-

13 HOL00002232 (Contura's "Instructions for Use" – stating that users determine the appropriate source

14 lumens, dwell positions and dwell times). Indeed, SenoRx markets the Contura as a device capable of

15 operating in the same way as Hologic's MammoSite from a central dwell position. Su Decl., Ex. D at

16 SRX-HOL00006665 REDACTED

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18 For this reason, SenoRx suggests that physicians use the Contura REDACTED

19 Su Decl., Ex. E at SRX-HOL00006684, 86 (SenoRx Sales Training Manual and FAQs).

20 Whatever the Contura's typical *use* may be – and in fact, the evidence suggests that employing

21 a central dwell point *is* a typical use – the evidence demonstrates that SenoRx manufactures a device

22 that provides for the placement of a radionuclide at the balloon's center point to perform

23 brachytherapy. From that location, the spacing between the inner spatial volume and the Contura

24 balloon wall is "constant in all directions" (Hologic's construction of "constant spacing"). Because the

25 user can stop the radionuclide in that central location for however long (s)he chooses, the Contura

26 exhibits a "fixed" spacing such that, for each point on the radionuclide, the distance to the nearest point

27 on the balloon wall is "the same" (SenoRx's construction of "constant spacing"). Thus, SenoRx

28 infringes under either party's construction. The fact that the Contura may not infringe if used to

1 irradiate tissue from *other* locations (*i.e.*, that SenoRx infringes the “predetermined constant spacing”
2 claims only *part of the time*) is irrelevant. *Bell Comm’s Research, Inc. v. Vitalink Comm’s Corp.*, 55
3 F.3d 615, 622-3 (Fed. Cir. 1995) (an accused product that sometimes, but not always, embodies a
4 claim nonetheless infringes).

5 **2. Not Only Is the Contura Capable of Performing Brachytherapy**
6 **From a Central Dwell Position – SenoRx and Others Have Used It In**
7 **That Way**

8 In addition to manufacturing a device meeting the “predetermined constant spacing” claim
9 term, SenoRx and others *have used* the Contura to emit radiation from a central dwell position within
10 the balloon wall. Therefore, SenoRx has infringed by both (a) making an apparatus meeting the
11 elements of claim 1 – including the “constant spacing” limitation, and (b) using the device to irradiate
12 tissue from a central dwell position. 35 U.S.C. § 271(a) (“... whoever without authority makes, *uses*
13 ... any patented invention ... infringes the patent.”).

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25 As stated, from a dwell point at or near the center of the Contura’s central treatment lumen, the
26 Contura exhibits a constant spacing in all directions between the inner spatial volume and the balloon
27 wall (Hologic’s construction). From that dwell position, it also exhibits a “fixed” spacing such that,
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1 for each point on the radionuclide, the distance to the nearest point on the balloon is substantially the
 2 same in all directions (SenoRx's construction). Thus, not only *can* the Contura be used in a manner
 3 that meets the "constant spacing" limitation, SenoRx, its paid consultants, and others have undeniably
 4 used it in this manner. Therefore, the Contura meets the "constant spacing" limitation of the '813
 5 patent. 35 U.S.C. § 271(a); *Wood-Paper Patent* (1874) 90 U.S. 566, 23 Wall 566, 23 L. Ed. 31 (a
 6 single instance of unauthorized use constitutes infringement).

7 **3. In Addition to Using a Central Dwell Point During a Multi-Dwell**
 8 **Point Procedure, Users Can and Have Used the Contura To Deliver**
 9 **Radiation From a Single, Central Position**

10 The fact that medical professionals decide which lumens, dwell positions, and dwell times to
 11 employ depending on the desired radiation dose profile, means that a user can opt for a single, fixed
 12 dwell position at the center of the Contura balloon. Using such a treatment plan, the Contura clearly
 13 meets the "predetermined constant spacing" limitation of claim 1 of the '813 patent.

14 It is well-established that imperfect practice of an invention does not avoid infringement.
 15 *Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003) (citing *Bell*
 16 *Comm's Research, Inc. v. Vitalink Comm's Corp.*, 55 F.3d 615, 622-3); *Hilgraeve Corp. v. Symantec*
 17 *Corp.*, 265 F.3d 1336, 1343 (Fed. Cir. 2001) (an accused device may be found to infringe if it is
 18 reasonably capable of satisfying the claim limitations, even though it may also be capable of non-
 19 infringing modes of operation); *Intel Corp. v. U.S. Int'l Trade Commission*, 946 F.2d 821, 832 (Fed.
 20 Cir. 1991) (regardless the intended use, an accused device infringes if capable of being used in
 21 infringing manner); *Paper Converting Machine Co. v. Magna-Graphics Corp.* 745 F.2d 11, 20 (Fed.
 22 Cir. 1984) ("that the machine was not operated in its optimum mode is inconsequential; imperfect
 23 practice of an invention does not avoid infringement"); 35 U.S.C. § 271(a) (prohibiting any and all
 24 uses of a patent invention).

25 In *Intel*, the patentee alleged infringement of a claim disclosing an integrated circuit of read-
 26 only memory with a programmable selection means for selecting an alternative addressing mode. 946
 27 F.2d at 831. The International Trade Commission ruled that defendant infringed the asserted claim
 28 because the accused device was capable of being used in a manner that embodied each claim

1 limitation, even though the device was not intended for such use. *Id.* at 831-32. On appeal, defendant
2 challenged the finding of infringement on the grounds that defendant never contemplated or intended
3 for the accused device to be sold or operated in an infringing manner. *Id.* In affirming the judgment,
4 the Federal Circuit stated:

5 [Defendant] also contends that the Commission's finding of infringement . . . is incorrect
6 because, although [defendant's devices] are *capable* of performing page mode addressing, the
7 [devices] were never sold to operate in page mode. No customer was ever told how to convert
8 the chip to page mode operation – or even that such conversion was possible. [Defendant]
9 argues that an alleged infringer must intend its parts to be used in an infringing fashion
10 ***There is no intent element to direct infringement [T]he accused device, to be
infringing, need only be capable of operating in the page mode. Contrary to [defendant's]
argument, actual page mode operation in the accused device is not required. (Id.
[emphasis added].)***

11 Here, as in *Intel*, there can be no genuine dispute that Contura users can select a treatment
12 program calling for the emission of radiation from a single location directly or nearly directly in the
13 center of the balloon. Indeed, SenoRx's own marketing materials expressly contemplate such use. As
14 the figure below depicts, REDACTED

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1 **REDACTED** For this additional reason, SenoRx’s device meets the “constant spacing” limitation of the
 2 ‘813 patent because, regardless of its intended or typical use,⁸ users can use it to perform radiotherapy
 3 from a single, stationary location, including a point directly or nearly directly at the balloon’s center.
 4 From that location, the Contura exhibits a constant spacing between the inner spatial volume and the
 5 balloon wall in all directions (Hologic’s construction). Further, from each point on the radionuclide to
 6 the nearest point on the balloon wall – the distance is the same (SenoRx’s construction). Therefore,
 7 SenoRx infringes under either party’s construction.

8 4. Whether SenoRx’s I-192 Seeds Are “Cylindrical” Rather Than 9 Spherical Is Irrelevant

10 Recognizing that both it and other users can use (and have used) the device to perform
 11 radiotherapy from a centrally-located position within its central treatment lumen (whether solely from
 12 that location or in conjunction with other dwell points), SenoRx argues that the Contura nonetheless
 13 cannot meet the “constant spacing” element because the Ir-192 radionuclides used with the Contura are
 14 *cylindrical* rather than spherical in shape. Dkt. No. 131 at 15 (Motion). According to this argument, if
 15 the Court adopts SenoRx’s construction of “inner spatial volume” (which requires a radionuclide
 16 *sphere*), SenoRx cannot infringe the “constant spacing” limitation because the distance from each
 17 point on the radionuclide to the nearest point on the Contura’s spherical balloon wall will not be “the
 18 same.” *Id.* at 14. This argument has no merit. Even if the Court were to adopt SenoRx’s constructions
 19 of *both* (1) the term “predetermined constant spacing . . .” and (2) the term “inner spatial volume” –
 20 SenoRx would still infringe.

21 *First*, in distinguishing between cylindrical and spherical radionuclides, SenoRx attempts to
 22 impose a degree of exactitude that both the ‘813 and ‘204 patents expressly state is not necessary.
 23 Both patents refer to an apparatus exhibiting a “substantially” or “generally” constant spacing between
 24 the inner spatial volume and the outer wall. ‘813 Patent, col. 1:55-57 (“the distance from the spatial
 25 volume and the wall is maintained *substantially* constant over their entire surfaces.”); col. 3:10-13
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27 ⁸ Indeed, as shown above, SenoRx’s own marketing documents indicate that such infringing use *is*, in
 28 fact, intended and recommended.

(spacing should be “**generally** constant”); col. 4:13-16 (“In either the concentric spherical embodiment of FIG. 1 or the non-spherical configuration of FIG. 3, the spacing between the inner and outer chambers needs to be held **somewhat** constant to avoid “hot spots.”); ‘204 Patent, col. 5:25-26 (spacing should be “**generally** constant”). By definition, the words “substantially,” “generally” and “somewhat” do not require exactitude. In the same way that the ‘813 patent term “uniform” does not mean *exactly* uniform, the ‘813 patent term “constant” does not mean *exactly* constant. Thus, under Hologic’s construction of “predetermined constant spacing,” using cylindrical radionuclides still infringes because, from a central location within the central lumen, the distance from each point on the surface of the radionuclide to the balloon wall is substantially constant in all directions. Likewise, under SenoRx’s construction, the distance from each point on the radionuclide surface to the balloon wall is substantially the same in all directions.

Further, from the perspective of one of ordinary skill in the art, the distance from each point on the outer edge of a cylindrical radionuclide to the balloon wall *is* effectively the same in all directions. Dkt. No. 145, ¶¶ 5, 12 (Verhey declaration). The radioactive sources contemplated in the ‘813 patent, whether spherical or cylindrical, are very small compared to the typical 40-60 mm diameter of a surgical cavity. *Id.*; Su Decl., Ex. N (5/20/08 Stubbs Depo. Tr. at 60:19-61:07) (standard brachytherapy radionuclides can be as small as 1 millimeter in width and 3 millimeters in length); *see also* Ex. J at SRX-HOL00006598-9 **REDACTED** No matter the shape, the radionuclides that the Contura uses are effectively point sources relative to the diameter of the inflated balloon. Dkt. No. 145, ¶ 12 (Verhey declaration). Indeed, brachytherapy balloons and the lumpectomy margins into which they are inserted may be generally spherical in shape, but are never perfect spheres. *Id.* at ¶ 5. Therefore, the distances from different points on a radionuclide to the outer balloon will never be exactly the same. *Id.* From a dosimetric standpoint, however, one skilled in the art would consider the minute differences in distance from each point on the outer edge of a cylinder-shaped radionuclide to the balloon wall to be trivial and insignificant – *i.e.*, the distances for all intents and purposes are the same. *Id.*

1 brachytherapy device; it is specially designed for the purpose of being combined by users with a
 2 radiation source to create the patented invention. Su Decl., Ex. O REDACTED Customers do
 3 not buy the Contura unless they intend to use it as a device for the delivery of radiation. SenoRx
 4 contemplates the use of commercially available remote afterloaders with the Contura device for
 5 placement of the radionuclides. Su Decl., Ex. C at SRX-HOL00002232 (Contura Instructions for Use:
 6 “Lumens are provided for attachment to commercially available HDR remote afterloader equipment
 7 for passage of the radiation source delivery wire”).

8 The substantial non-infringing use exception to § 271(c) does not apply. That exception
 9 applies to staple articles of commerce – which the Contura is not. *University of California v. Hansen*
 10 54 USPQ 2d 1473 at *25-26 (1999, E.D. CA) (occasional aberrant use of product that is clearly
 11 designed to be used in particular matter [*sic*] does not make defendant’s device staple article or
 12 commodity of commerce suitable for substantial non-infringing use) (finding defendants liable for
 13 infringement under § 271(a), (b), and (c)). In any event, minus the radiation, the Contura has no
 14 substantial non-infringing uses because its only utility is as a radiation therapy device in accordance
 15 with the invention.

16 Based on the foregoing, far from militating *against* infringement, a reasonable jury could and
 17 would conclude that SenoRx infringes the asserted claims, both directly and indirectly.

18 **III. SENORX’S ACCUSED PRODUCT MEETS THE “PREDETERMINED SPACING”** 19 **LIMITATION OF THE ‘204 PATENT (CLAIM 4)⁹**

20 Unlike the ‘813 patent, which requires a “predetermined *constant* spacing,” the ‘204 patent
 21 requires only a “*predetermined spacing . . .*” col. 8:40. SenoRx contends these two terms mean the
 22 same thing. They do not. The Court previously construed both terms and found that they convey
 23 different meanings. Su Decl., Ex. B at 6-7, 24-25. The Court’s prior construction and the parties’
 24 proposed constructions are set forth below:

25
 26
 27 ⁹ Claim 4 of the ‘204 patent depends from claim 3, which contains the “predetermined spacing”
 28 language.

Term	Hologic's Construction (the Court's prior construction)	SenoRx's Construction
"predetermined spacing ...between said inner spatial volume and the expandable surface element" (claim 3)	the distance between the inner spatial volume and the expandable surface element is determined in advance	Fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the wall of the expandable surface element, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the expandable surface element is the same (i.e., the inner spatial volume and expandable surface element are concentric and the same shape).

A. SenoRx Has Not Moved for Summary Judgment Under Hologic's Construction.

If the Court adopts Hologic's construction of the term "predetermined spacing . . ." (*i.e.*, if the Court adopts its own prior construction), SenoRx's Motion with respect to claim 4 of the '204 patent is moot. SenoRx has not moved for summary judgment under Hologic's construction.

B. SenoRx Meets the "Predetermined Spacing . . ." Limitation Even Under Its Own Construction

Because SenoRx believes the terms "predetermined *constant* spacing . . ." ('813 patent) and "*predetermined spacing* . . ." ('204 patent) mean the exact same thing, the same infringement analysis discussed above (regarding direct *and* indirect infringement) applies to both. Under SenoRx's proposed construction, the Contura meets the "predetermined spacing" limitation of the '204 patent because (1) SenoRx manufactures the Contura (Section II(A)(1), above); (2) SenoRx and others have used the Contura with a central dwell position in its central treatment lumen (Section II(A)(2), above); and (3) SenoRx and others can and have performed radiotherapy with the Contura using a single, central location in the central treatment lumen (Section II(A)(3), above). Therefore, under SenoRx's proposed construction, the "predetermined spacing" limitation of the '204 patent is met. *See also* sections II(B) and II(C), above (discussing SenoRx's indirect infringement of the asserted claims).

\\

IV. THE CONTURA MEETS THE “PLURALITY OF RADIOACTIVE SOLID PARTICLES” ELEMENT OF CLAIM 12 OF THE ‘813 PATENT, AND THE “PLURALITY OF SOLID RADIATION SOURCES” ELEMENT OF CLAIM 17 OF THE ‘204 PATENT

A. SenoRx Literally Infringes Under Hologic’s Claim Construction

SenoRx’s Contura device literally meets the “plurality of radioactive solid particles / solid radiation sources” claim elements of the ‘813 and ‘204 patents because a solid radionuclide on a source wire can be (and is) inserted sequentially into multiple predetermined locations within one or more of the Contura’s treatment lumens to provide a “desired composite radiation profile” within the targeted tissue. *See* Dkt. No. 131-6, Ex. A at 15 (Hologic’s Infringement Contentions).

SenoRx’s misguided argument that use of the word “plurality” requires the presence of “two or more” separate and distinct radionuclides in the device “at the same time” (and its mischaracterization of Hologic’s position as being that “plurality” means “one”) is a classic example of attempting to construe a claim term in isolation – divorced from both the claim language in which it appears and the remainder of the specification. *See* Dkt. No. 144 at 22-25 (Hologic’s Reply Claim Construction Brief); Dkt. No. 131 at 8 (SenoRx’s Motion, arguing that even under SenoRx’s construction of these terms, “. . . [t]he act of moving a single radionuclide to multiple locations does not transform the single object into two or more objects . . .) The argument has no merit.¹⁰

SenoRx’s non-infringement argument violates a fundamental principle of claim construction reaffirmed by the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), that one cannot import aspects of preferred embodiments into the claims by requiring that discrete radiation sources be present and used simultaneously. *Id.* at 1323; *see* Dkt. No. 144 at 23 (Hologic’s Reply Claim Construction Brief). Read together with the surrounding claim language and in light of the specification, the objective of these claims (claim 12 of the ‘813 and claim 17 of the ‘204) is to

¹⁰ SenoRx takes issue with the Court’s previous ruling regarding the meaning of this claim language. The Court previously considered the phrase “plurality of radioactive solid particles placed at predetermined locations . . . to provide a desired composite radiation profile” (‘813 patent, claim 12) and decided that it means what it says – *i.e.*, no construction is necessary. *Su Decl.*, Ex. B at 11-12. Hologic agrees.

1 differentiate embodiments in which (1) diseased tissue is irradiated from a *single* location from (2) an
2 embodiment in which radiation is emitted from *multiple locations* (hence the use of the term
3 “plurality”) in order to achieve a “composite radiation profile” (‘813 patent, claim 12) and a “desired
4 resultant profile” (‘204 patent, col. 5:12). SenoRx’s contention that the Contura cannot meet these
5 claim elements because Figure 5 of the ‘813 patent and Figure 4 of the ‘204 patent show multiple solid
6 radionuclides present at the same time violates the Federal Circuit’s clear mandate in *Phillips*. 415
7 F.3d 1303. If SenoRx’s reasoning were sound, any patent defendant could simply scour the
8 specification for a disclosed embodiment that differs from the accused product – and proceed to argue
9 non-infringement as a matter of law.

10 The admissions and diagrams in SenoRx’s own Motion illustrate that the Contura meets the
11 “plurality . . .” claim elements. SenoRx states that “the undisputed evidence is that in every case of
12 patient treatment since the commercial launch of the Contura in January 2008, the [radiation] dose was
13 delivered with multiple dwell positions.” Dkt. No. 131 at 15 (Motion) (*see* Figure 4, illustrating how
14 the Ir-192 radionuclides used with the Contura can be moved sequentially to multiple locations within
15 the balloon – such that radiotherapeutic rays may be emitted from numerous positions to achieve a
16 desired composite radiation profile). Thus, under the plain meaning of claim 12 of the ‘813 patent and
17 claim 17 of the ‘204 patent, by SenoRx’s own admission, the Contura reads on the claim language
18 directly – thereby literally infringing the claims.

19 SenoRx inserts a secondary argument (Dkt. No. 131 at 8) that it does not manufacture the
20 iridium-192 radionuclides used with the Contura and therefore does not meet the disputed claim terms.
21 This argument is spurious – the very purpose of the Contura is to “deliver therapeutic radiation to
22 target tissue.” Dkt. No. 131 at 3 (SenoRx’s Motion). SenoRx only manufactures, markets and sells the
23 Contura so that it can be used with radionuclides to perform brachytherapy; it has no purpose or
24 usefulness without them. In any event, under 35 U.S.C. § 271(a), SenoRx infringes if it “makes, uses,
25 offers to sell, or sells . . .” an infringing device in the United States. Even under SenoRx’s argument
26 that it does not “make” radionuclides – it still infringes because both it **REDACTED** have used the
27 Contura with Ir-192 radionuclides. Su Decl., Ex. J at SRX-HOL00006598 **REDACTED**
28

1 REDACTED

Ex. E at SRX-

2 HOL00006684

REDACTED

3 *AdvanceMe Inc. v. RapidPay, LLC*, 509 F. Supp. 2d 593, 605 (E.D. Tex 2007) (“Liability for direct
4 infringement cannot be avoided by interposing an agent or independent contractor between the
5 defendant and the infringing acts.”) Thus, SenoRx has both “made” and “used” the patented invention.
6 35 U.S.C. § 271(a). Viewing the evidence of SenoRx’s testing and use of the device in a light most
7 favorable to Hologic, and resolving all inferences in its favor, SenoRx infringes.

8 Further, and for the same reasons it indirectly infringes the asserted claims of the ‘813 and ‘204
9 patents containing the “predetermined constant spacing” and “predetermined spacing” limitations,
10 SenoRx indirectly infringes the asserted claims containing the “plurality” limitations. 35 U.S.C. §
11 271(b) and (c). *See* sections II(B) and II(C), above.

12 **B. Under SenoRx’s Claim Construction, SenoRx Infringes Under the Doctrine of**
13 **Equivalents¹¹**

14 **1. Legal Standard for Doctrine of Equivalents**

15 A product that does not literally infringe may nonetheless be found to infringe if there is
16 “equivalence” between the elements of the accused product and the claimed elements of the patented
17 invention. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). The doctrine
18 applies where the differences between the patented invention and the accused device are insubstantial.
19 *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 726 (2002). One way to make
20 this determination is to consider whether the accused device performs substantially the same function
21 in substantially the same way to obtain substantially the same result. *See Depuy Spine, Inc. v.*
22 *Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1019-1020 (Fed. Cir. 2006) (reversing judgment of
23
24

25 ¹¹ Hologic has reserved its right to amend its preliminary infringement contentions to the
26 extent that any element of any asserted claim is determined not to be literally present after a final
27 ruling on claim construction. Dkt. No. 131-6, Ex. A at 1, fn 2 (Hologic’s Preliminary Infringement
28 Contentions); *see* N.D. Cal. Pat. L.R. 3-6(a)(1) (Jan. 1, 2001 rev.) (granting right to amend without
leave the information under Patent Local Rule 3-1(d) based on the Court’s claim construction) (the
March 1, 2008 Patent Local Rules do not apply to this case).

1 non-infringement and finding that triable issue of fact existed as to whether accused device infringes
2 under the doctrine of equivalents).

3 Equivalence is not the prisoner of formula and is not an absolute to be considered in a vacuum.
4 *Warner-Jenkinson*, 520 U.S. at 24. It does not require complete identity for every purpose and in
5 every respect. *Id.* Even things that are, for most purposes, different, may sometimes be equivalents.
6 *Id.*; *Caterpillar, Inc. v. Deere & Co.*, 224 F.3d 1374, 1379 (Fed. Cir. 2000) (as with literal
7 infringement, whether an accused device infringes under the doctrine of equivalents is a question of
8 fact).

9 **2. SenoRx Meets the “Plurality of Radioactive Solid Particles” and**
10 **“Plurality of Solid Radiation Sources” Elements Under the Doctrine**
11 **of Equivalents**

12 If the Court were to adopt SenoRx’s construction of the terms “plurality of radioactive solid
13 particles” (‘813 patent) and “plurality of solid radiation sources”(‘204 patent), summary judgment
14 would still be improper because under SenoRx’s constructions, the Contura meets these elements
15 under the doctrine of equivalents.

16 **Function.** The function of having “a plurality of radioactive solid particles placed at
17 predetermined locations within the inner spatial volume to provide a desired composite radiation
18 profile” is to provide a therapeutic dose of radiation to treat proliferative tissue disease. (‘813 patent,
19 claim 12; ‘204 patent, col. 5:10-12). The ‘813 and ‘204 patents state: “This invention relates generally
20 to [an] apparatus for use in treating proliferative tissue disorders, and more particularly to an apparatus
21 for the treatment of such disorders in the body by the application of radioactive material and/or
22 radiation emissions.” Dkt. No. 135-2 (‘813 patent, col. 1:7-11); Dkt. No. 135-3 (‘204 patent, col. 14-
23 17 [same, using slightly different language].) Further, the purpose of an embodiment emitting
24 radiation from more than one location is to achieve a “desired composite radiation profile.” *See* ‘813
25 patent, claim 12, Figure 5; ‘204 patent, col. 5:1-12 (radiation emitted from multiple locations “to
26 generate a desired resultant profile”); Fig. 4.

1 The function of the Contura is the same -- to deliver radiation to target tissue to treat
 2 proliferative tissue disease. Su Decl., Ex. C at SRX-HOL00002232 (Instructions for Use: “Contura ...
 3 is intended to provide brachytherapy . . . to deliver intracavitary radiation to the surgical margins
 4 following lumpectomy for breast cancer”). Where a treatment plan calls for multiple dwell points, the
 5 Contura serves to generate a desired resultant profile. *See* Dkt. No. 131 at 14-15 (SenoRx’s Motion
 6 describing Contura radionuclide moving to different locations within the balloon); Su Decl., Ex. S at
 7 SRX-HOL00005403 (Contura MLB Brachytherapy Applicator Clinical Data Report - REDACTED

8
 9 Su Decl., Ex. J at SRX-HOL00006598-6601 (Contura

10 REDACTED

11
 12 **Way.** The claimed apparatus and the Contura serve to generate a desired composite radiation
 13 profile in substantially (if not exactly) the same way. As set forth in the written descriptions and as
 14 illustrated by the drawings (‘813 patent, Fig. 5; ‘204 patent, Fig. 4), one way to generate a desired
 15 resultant profile is to mount multiple particles 44 on the distal ends of a plurality of wires 46 that are
 16 routed through the catheter body 12 . . . reaching the lumen. ‘204 patent, col. 5:1-12. As SenoRx
 17 concedes, depending on the chosen treatment plan, the Contura may step an iridium-192 radionuclide
 18 through multiple locations within one or more treatment lumens – the cumulative result constituting
 19 the desired composite radiation profile. *See* Dkt. No. 131 at 12-15 (including Figs. 2-4) (describing
 20 how the Contura may employ multiple dwell points); Su Decl., Ex. E at SRX-HOL00006685 REDACTED

21
 22
 23 As Dr. Verhey has explained, the Contura achieves a composite profile in the same way – or at
 24 a minimum, in substantially the same way. Dkt. No. 145 at ¶¶ 27-31 (Verhey declaration supporting
 25 Hologic’s Reply Claim Construction Brief). One of ordinary skill in the art would understand that one
 26 can achieve a “desired composite radiation profile” by using a single particle or source and moving it
 27 to multiple locations, or using multiple particles or sources in predetermined locations. *Id.* at ¶ 28.

1 From a dosimetric standpoint, *there is no distinction* between moving one radionuclide to multiple
 2 locations versus the embodiment depicted in Figure 5 of the '813 patent and Figure 4 of the '204
 3 patent. *Id.*

4 **Result.** Finally, both the claimed inventions and the Contura actually result in a composite
 5 radiation profile that serves to kill proliferative tissue cells such as cancer cells without causing an
 6 undue risk of tissue necrosis. '813 patent, col. 1:42-46 (the instrument "may be used to deliver
 7 radiation from a radioactive source to target tissue within the human body of a desired intensity . . .
 8 without overexposure of body tissues disposed between the radiation source and the target"); '204
 9 patent, col. 2:28-33 (same); Su Decl., Ex. T at SRX-HOL00001536-7 (Contura Product Overview and
 10 Dosimetry - REDACTED

11
 12 In light of the evidence produced to date, a reasonable jury would find (or certainly could find)
 13 that the Contura performs substantially the same function as the inventions set forth in claim 12 of the
 14 '813 patent and claim 17 of the '204 patent, in substantially the same way, to achieve substantially the
 15 same result.

16 **V. IN ANY EVENT, SENORX'S MOTION MUST BE DENIED**

17 Even if the Court were to disagree with each of Hologic's infringement arguments set forth
 18 above and conclude that SenoRx's accused device does not meet the disputed claim terms, SenoRx's
 19 Motion would still lack merit. Infringement, whether literal or under the doctrine of equivalence, is a
 20 question of fact. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326 (Fed.
 21 Cir. 2007). All justifiable inferences must be drawn in Hologic's favor. *Id.* The evidence produced by
 22 SenoRx to date indicates, if it does not conclusively show, that the Contura meets the "predetermined
 23 spacing" and "plurality . . ." elements of the patents-in-suit. Therefore, SenoRx's Motion must be
 24 denied. While the jury ultimately may reject Hologic's arguments at trial, the infringement decision
 25 should not be taken from them. *Id.*

1 **VI. HOLOGIC REQUESTS THE RIGHT TO SUPPLEMENT ITS OPPOSITION WITH**
2 **RELEVANT EVIDENCE**

3 While Hologic believes the evidence presented definitively precludes summary judgment in
4 favor of SenoRx, Hologic requests the right to supplement its Opposition with evidence discovered
5 prior to the June 25, 2008 hearing. *See* Fed. R. Civ. P. 56(c) (permitting an opposing party to serve
6 opposing affidavits before the hearing day).

7 **VII. CONCLUSION**

8 For the foregoing reasons, SenoRx's Contura meets the "predetermined constant spacing. . .,"
9 "predetermined spacing . . .," "plurality of radioactive solid particles . . .," and "plurality of solid
10 radiation sources" limitations of the '813 and '204 patents. At the very least, the evidence precludes
11 entry of summary judgment for SenoRx. Hologic respectfully requests that SenoRx's Motion be
12 denied.

13 Dated: June 4, 2008

HOWREY LLP

14
15
16 By: /s/
Henry C. Su

17
18 HOWREY LLP
19 Attorneys for Plaintiffs
20 Hologic, Inc., Cytoc Corporation,
and Hologic LP
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PROOF OF SERVICE

I am employed in the County of San Mateo, State of California. I am over the age of 18 and not a party to the within action. My business address is 1950 University Avenue, 4th Floor, East Palo Alto, California 94303.

On June 4, 2008, I served on the interested parties in said action the within:

PLAINTIFFS' OPPOSITION TO DEFENDANT SENORX, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT ('813 PATENT, CLAIMS 11 & 12; '204 PATENT, CLAIMS 4 & 17; AND '142 PATENT, CLAIM 6) (PUBLIC VERSION with exhibits and CONFIDENTIAL VERSION with SEALED EXHIBITS A, D THROUGH P, S, AND T); DECLARATION OF HENRY C. SU IN SUPPORT OF OPPOSITION TO SENORX, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT ('813 PATENT, CLAIMS 11 & 12; '204 PATENT, CLAIMS 4 & 17; AND '142 PATENT, CLAIM 6); MANUAL FILING NOTICE; CIVIL LOCAL RULE 79-5(B) AND (C) ADMINISTRATIVE MOTION TO FILE UNDER SEAL EXHIBITS A, D THROUGH P, S, AND T TO THE DECLARATION OF HENRY C. SU IN SUPPORT OF OPPOSITION TO SENORX, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT ('813 PATENT, CLAIMS 11 & 12; '204 PATENT, CLAIMS 4 & 17; AND '142 PATENT, CLAIM 6); and [PROPOSED] ORDER GRANTING PLAINTIFFS' ADMINISTRATIVE MOTION TO FILE UNDER SEAL

by placing a true copy thereof in a sealed envelope(s) addressed as stated below and causing such envelope(s) to be deposited in the U.S. Mail at East Palo Alto, California.

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☒ (MAIL) I am readily familiar with this firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. postal service on that same day in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than 1 day after date of deposit for mailing in affidavit.

☒ (EMAIL/ELECTRONIC TRANSMISSION) Based on a court order or an agreement of the parties to accept service by e-mail or electronic transmission, I caused the documents to be sent to the persons at the e-mail addresses listed above. I did not receive, within a reasonable time after the submission, any electronic message or other indication that the transmission was unsuccessful.

I declare under penalty of perjury that I am employed in the office of a member of the bar of this Court at whose direction the service was made and that the foregoing is true and correct.

Executed on June 4, 2008, at East Palo Alto, California.

Sonya Schwab
(Type or print name)


(Signature)